

**CMDh Task Force  
Meeting on  
Self-Medication  
- Non-prescription medicines -**

**Agenda item #2**

**20 June 2011**

# PART I

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## LEGAL STATUS

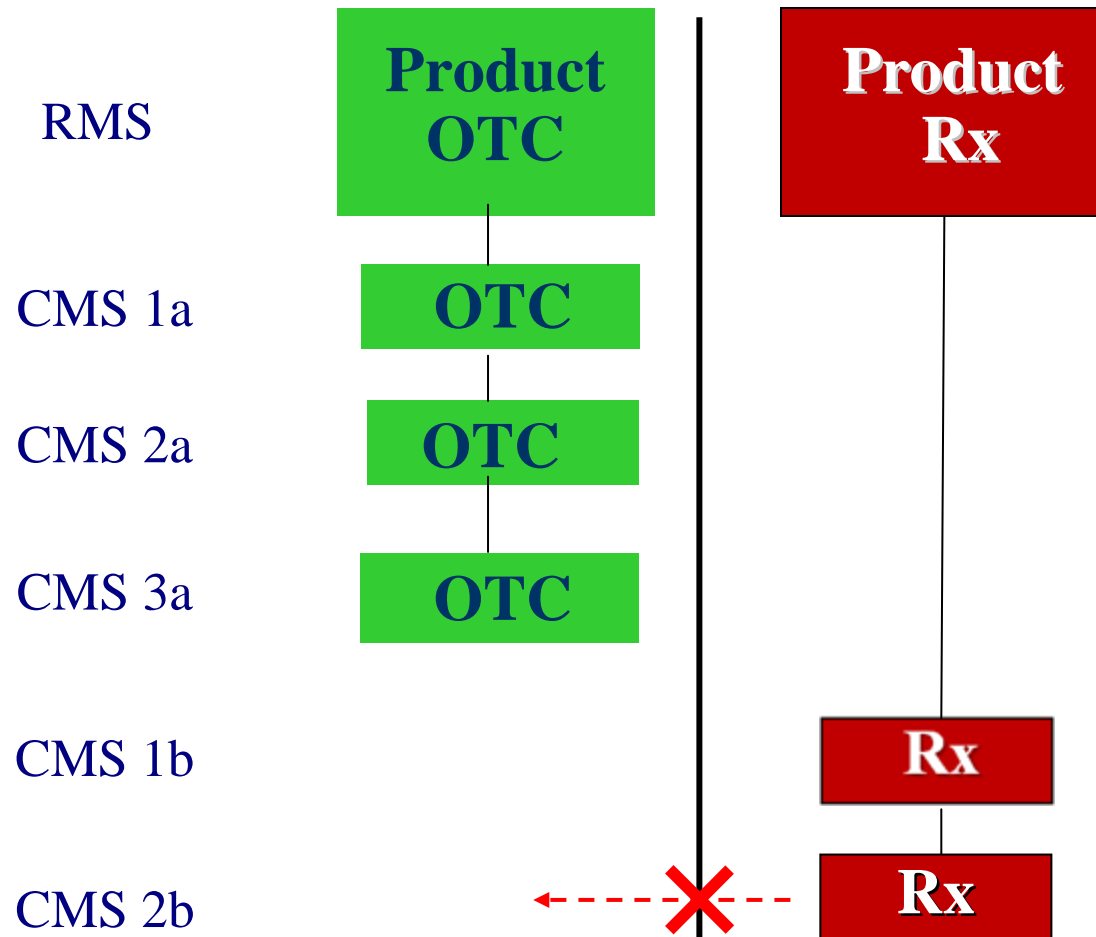
# Introduction

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- Legal status (prescription vs. non-prescription) outside of summary of product characteristics
  - Decision on legal status subject to national authority approval
  - Product information (SmPC + labelling) linked to legal classification
- Although legal status per se not part of MRP/DCP, it is an integral part of the discussion due to impact on harmonised product information.

# Current most frequent scenario: separate OTC and Rx MRP/DCP

- ⇒ Harmonised product information for each: procedure a (non-prescription) and for procedure b (prescription). Reclassification of product in procedure b prevented by disharmony of product information.
- ⇒ Pre-condition: dual legal status in RMS or different RMS needed



# Consequences of separate OTC and Rx MRP/DCP in terms of reclassification

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RMS of procedure 2 (red - Rx) should be open to potential label changes to allow for:

- Rx to OTC switches in CMSs
  - Data collection in real-life setting to enable switch in Member States requesting those data
- Rarely accepted as causing changes to harmonised product information outcome of the MRP/DCP

# Consequences of separate OTC and Rx MRP/DCP in terms of reclassification

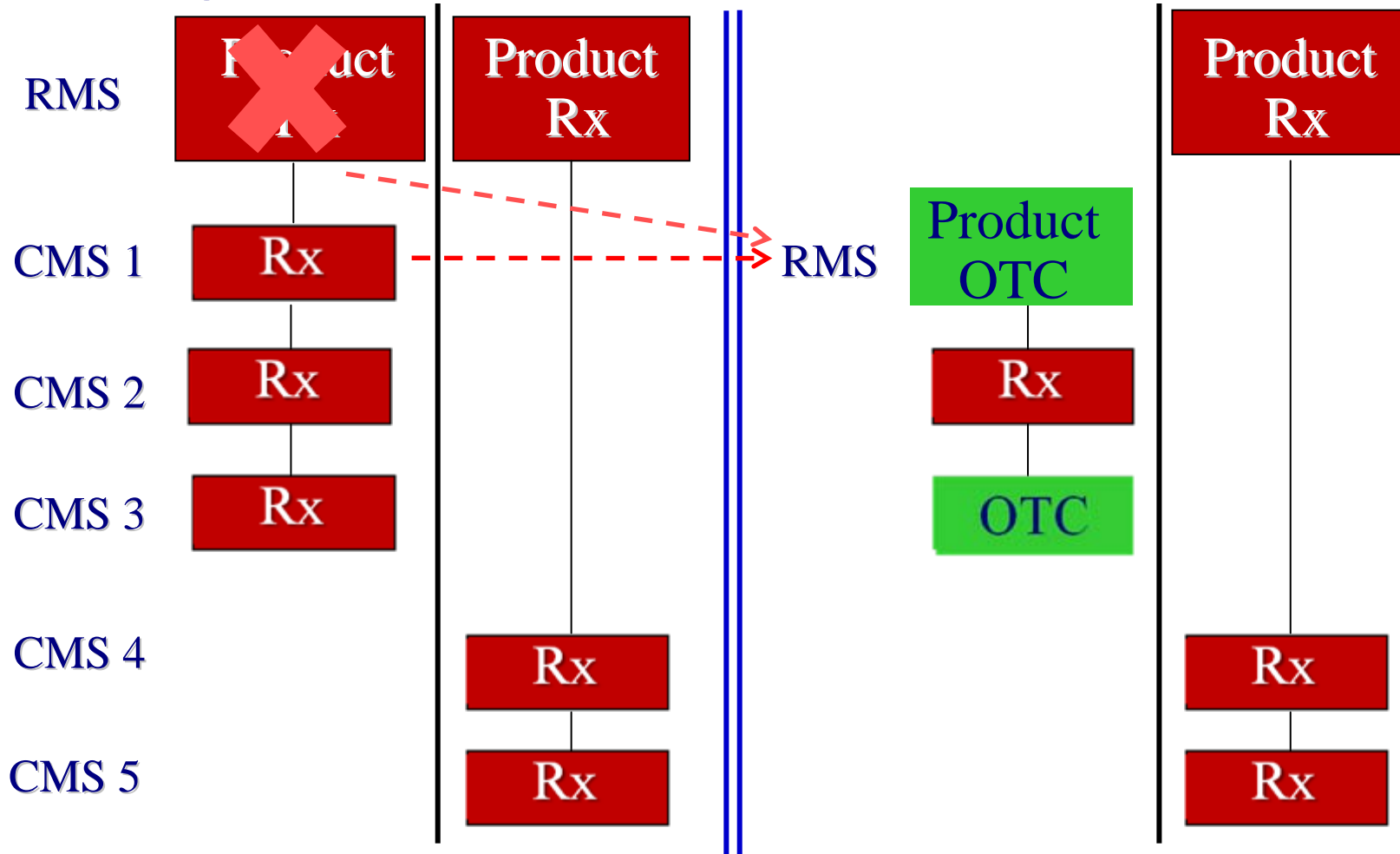
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If RMS does not agree with label changes

- Change in prescription status (to non-prescription) in other Member States will not be possible
- Alternatively, the applicant would need to change RMS and withdraw the MA in the RMS

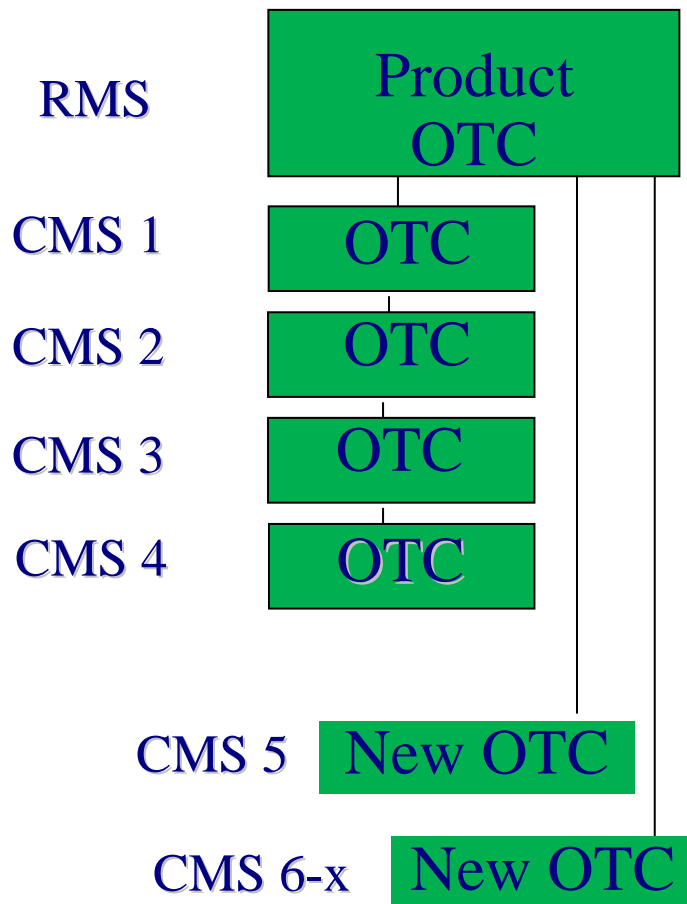
# Consequences of separate OTC and Rx MRP/DCP in terms of reclassification

⇒ Change of RMS in one MRP/DCP line and withdrawal of MA in RMS



# Consequences of separate OTC and Rx MRP/DCP in terms of reclassification

⇒ Repeat-use MRP country by country or in country groups once substance becomes OTC, but lengthy and risks for existing markets!



# AESGP Proposed solution: Combined Rx/OTC MRP/DCP, subset of product information

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RMS & CMSs to allow for differentiation of ‘Rx’ and ‘OTC’ in the Product Information

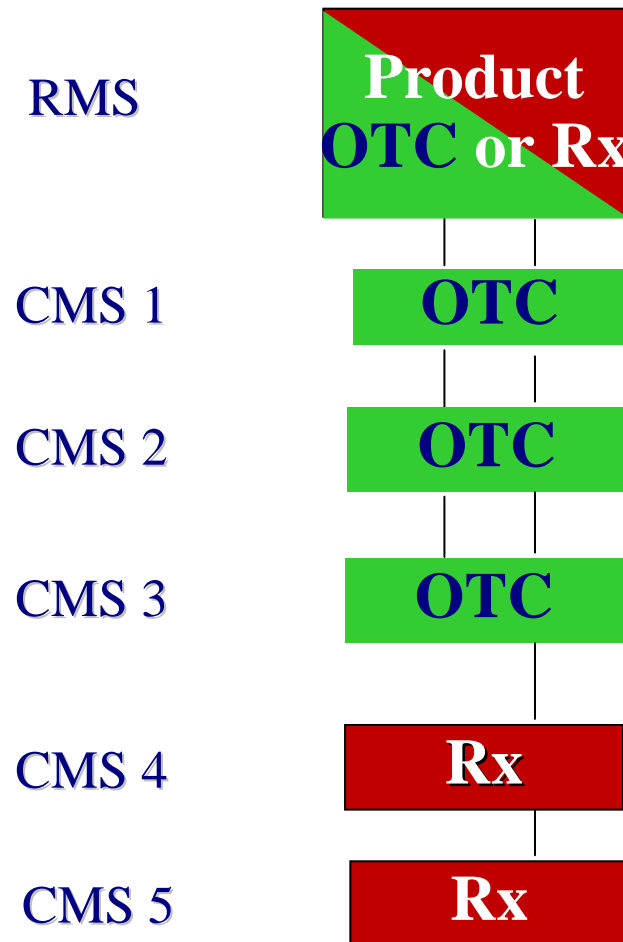
- **“Sub-sets of product information”**
  - own SmPC and version of PIL suitable to OTC markets
    - > Precedence: omeprazole (2 product information, one specific to ‘Rx’, the other to non-prescription)
  - “blue box concept”
    - > Particular sections in SmPC/PIL specific to ‘Rx’ and non-prescription with national implementation of the respective applicable text

# AESGP Proposed solution: Combined Rx/OTC MRP/DCP, subset of product information

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⇒ Paves the way for further switches

⇒ Facilitated by Art. 30 harmonisation of product information (cf. Losec referral)



# Subset of product information: 2 solutions

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## Annex I/III which includes:

- **SmPC**

For medicinal products available on  
*prescription*

- **SmPC**

For medicinal products available  
*without prescription*

- **Package leaflets**

For medicinal products available on  
*prescription*

- **Package leaflets**

For medicinal products available  
*without prescription*

**OR**

- **SmPC (one single)**

- **Package leaflet**

**With sub-sections (as needed) if  
text different for**

<Prescription>

**and**

<OTC> **information**

# Clarity on legal status needed pre and post evaluation

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## - Pre-submission

- **Discussion** during pre-submission meeting

## - Post-evaluation

- **Decision** on the prescription status
  - Summary of the decision background should be provided by the respective Member State
- **Tracking of legal status**
  - Final outcome of legal status could be sent by the applicant at end of procedure
  - Should appear in the MRI Product Index
  - Information update on changes in prescription status could be provided by the applicant to RMS

# Part II

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## **OTHER SELF-CARE SPECIFIC ISSUES**

# 1. Pre-submission

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- **Pre-submission meetings for upfront agreement on submission and timing**
  - Meeting with proposed RMS
    - To be held at least 6 months prior to submission
    - Should replace slot booking
    - Agencies should be open to hold such meetings
    - Meeting should be voluntary for companies

# 1. Pre-submission (cont')

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- **Meeting purpose: alignment with RMS on:**
  - Regulatory strategy for submission & related timing
  - Strategy regarding legal status (non-prescription)
    - > Relevant assessors should have **knowledge of non-prescription medicines and switches** and be present at the meeting
    - > Proposed legal status in the Member States involved could be reflected in the application form as annex (similar to Annex 5.19)

# 1. Pre-submission (cont')

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- **Benefit of pre-submission meetings**
  - Establish **mutual interest** on working together on the application
    - > To ensure strong and supportive role of the RMS
    - > In case of negative outcome the applicant can look for another RMS

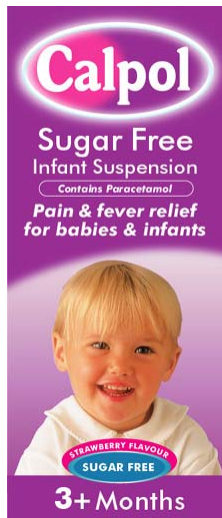
## 2. Evaluation

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- **Specific expertise/understanding of non-prescription medicines**
- Assessors attuned to non-prescription medicines particularities
  - **“OTC champion”**: Ideally, dedicated non-prescription contact point/unit within the agency
  - **Training/discussion** of challenging points in applications or recurrent questions in LOQ
    - > Twilight programme/exchange amongst the assessors within the agencies
    - > Joint training sessions with industry participation

# 3. Post-evaluation

- **National phase**
- Approval of **packaging and name** should be enhanced and the legal status be taken into consideration
  - Pack design is important for non-prescription medicines
  - Invented name, critical health information and pack design complement each other
    - > Packaging has to provide all information required for consumer to select an appropriate product, choose between products and use the product safely



# Key take-aways

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- We appreciate the Task Force initiative to address the specificities of non-prescription medicines in the DCP/MRP
- **Legal status is key** → outside of SPC but impacts all aspects of product information and influence MRP/DCP regulatory strategy
- Possibility of **product information sub-sets** reflecting non-prescription/prescription specificities as outcome of ‘mixed status’ MRP/DCP seen as best (and easy) solution
- **Mixed legal status MRP/DCP & product information sub-sets** together with **pre-submission meetings**, an “**OTC champion**” in each Agency and **understanding of importance of name and pack design** would make **MRP/DCP more attractive** and **optimise its use:**

*Helps patients access greater choice in self medication products and helps industry and regulatory agencies work more efficiently in meeting this goal together.*